4927. Amphetamine sulfate tablets. (F. D. C. No. 38281. S. Nos. 4-586/8 M.)

QUANTITY: 5 1,000-tablet btls., 1 500-tablet btl., and 1 50-tablet btl., at Vestal, N. Y.

SHIPPED: 7-18-55, from Youngstown, Ohio.

LIBELED: 8-15-55, N. Dist. N. Y.

CHARGE: 502 (f) (1)—the labeling of the article, while held for sale, failed to bear adequate directions for use, and it was not entitled to any exemption from that requirement.

DISPOSITION: 10-15-55. Default—destruction.

4928. Dexadex tablets. (F. D. C. No. 38267. S. Nos. 21-656 M, 21-797 M.)

QUANTITY: 2 1,000-tablet btls. and 647 100-tablet btls. at Philadelphia, Pa., in possession of Cabot Pharmaceutical Co.

SHIPPED: 6-10-54, from Cleveland, Ohio.

LABEL IN PART: (Btl.) "Cabot * * * Tablets Dexadex (Formerly Dexadel)

Each tablet contains Dextro-Amphetamine Sulfate 10 mg."

RESULTS OF INVESTIGATION: The tablets were shipped in bulk from Cleveland, Ohio, and upon their receipt by the consignee, they were repackaged and relabeled. Analysis showed that the article contained substantially less than the declared amount of dextro-amphetamine sulfate.

LIBELED: 8-3-55, E. Dist. Pa.

CHARGE: 501 (c)—the strength of the article, while held for sale, differed from that which it purported and was represented to possess; 502 (a)—the label statement "Each tablet contains Dextro-Amphetamine Sulfate 10 mg." was false and misleading; and 502 (f) (1)—the labeling of the article failed to bear adequate directions for use since its label failed to bear a statement of the recommended or usual dosage.

DISPOSITION: 9-29-55. Default—destruction.

4929. West-Lax tablets. (F. D. C. No. 38483. S. Nos. 29-593/4 M.)

QUANTITY: 1 10,000-tablet drum and 1 25,000-tablet drum and a number of empty boxes at East Orange, N. J., in possession of Olive May Co.

SHIPPED: 8-3-55 and 8-31-55, from Baltimore, Md., by Mineralized Foods, Inc.

Label In Part: (Drum) "West-Lax A Good Laxative Consists of an imported variety of West's Sea Vegetation (Edible Sea Plants) naturally laxative, carefully blended with Senna Fruit, ripe fruit of Cassia Fistula and Chinese Rhubarb, flavored with Peppermint Leaves * * * Manufactured by Mineralized Foods Inc., Baltimore Maryland * * * The Contents Of This Drum Is Intended For Re-Packaging and Re-Labeling By The Consignee"; (box) "Tablets number 206 1.00 Olive May Co. * * * Dietary Supplement."

RESULTS OF INVESTIGATION: The consignee intended to repackage the article from the drums into the empty boxes.

LIBELED: 10-10-55, Dist. N. J.

CHARGE: 502 (a)—the statement "Dietary Supplement" borne on the box label of the article, while held for sale, was false and misleading since the article was not a dietary supplement and possessed no dietary properties; 502 (f) (1)—the labeling of the article, when shipped and while held for sale, failed to bear adequate directions for use; and 502 (f) (2)—the labeling of the article, when shipped and while held for sale, failed to bear a warning

against use in case of nausea, vomiting, abdominal pains, or other symptoms of appendicitis, and a warning that frequent or continued use may cause a dependency upon laxatives to move the bowels.

DISPOSITION: 11-17-55. Default-destruction.

4930. Devine's Zina-Ray oil, Devine's Na-Zol ointment, and Devine's inhaler. (F. D. C. No. 37787. S. Nos. 14-317/8 M.)

QUANTITY: 210 2-dram vials, 393 1-oz. btls., 330 3-oz. btls., and 70 8-oz. btls. of Devine's Zina-Ray oil; 253 1-oz. jars of Devine's Na-Zol ointment; and 2,873 Devine's inhalers; also 1 ½-oz. btl. of cough syrup made with Devine's Zina-Ray oil; 1 1-oz. vial containing menthol; 1 1-oz. vial containing gum camphor; 1 1-oz. vial containing eucalyptus oil; 1 plaster plaque model of cross-section of the human head; 1 box with outline of cross section of the human head showing air passages and sinuses; one section of arthritic human vertebras; and one cut-away demonstration of human skull, at St. Louis, Mo., in possession of Howard Dean, demonstrator for Devine's Remedies, Inc., of Chicago, Ill.

SHIPPED: 1-30-54 and 1-12-55, from Chicago, Ill.

RESULTS OF INVESTIGATION: Howard Dean, in the course of a sales talk, recommended the *Devine's Zina-Ray oil* and *Devine's Na-Zol ointment* for use in the treatment of the diseases and conditions described below.

Examination disclosed that the oil and ointment had the odor of eucalyptus, camphor, and menthol. The inhaler was intended for use with the oil.

LIBELED: 2-14-55, E. Dist. Mo.

CHARGE: 502 (f) (1)—the labeling of *Devine's Zina-Ray oil* and of *Devine's Na-Zol ointment*, while held for sale, failed to bear directions for use in the treatment of the conditions for which such articles were intended, namely, (oil) headache, hay fever, rose fever, sore throat, tonsillitis, bronchitis, asthma, infected sinuses, soft flabby gums, arthritis, rheumatism, swollen, sore, stiff joints, and (ointment) sore throat.

DISPOSITION: 10-5-55. Consent—claimed by Devine's Remedies, Inc. A placard entitled "Ethmoid Labyrinth" and the above-mentioned box, with its contents, were delivered to the Food and Drug Administration. The above-mentioned drugs, inhalers, and plastic cut-away model of the human head, together with leaflets entitled "Pain Sufferers," were released to the claimant and shipped to its place of business at Chicago, Ill.

4931. Uranium ore. (F. D. C. No. 38262. S. No. 21–050 M.)

QUANTITY: 275 pads packed with ground uranium ore and 1,000 lbs. of loose uranium ore at Gordon, Nebr., in possession of Mrs. Peggy Bartow, t/a Uranium Center.

SHIPPED: During July 1954, from Pacho, Ariz.

RESULTS OF INVESTIGATION: The uranium ore was shipped in bulk, and, after receipt by the consignee, a portion was packed into the pads. The loose uranium ore was contained in the backs and seats of full length benches and in the ceiling of a room designated "the sitting room," located in the building housing the Uranium Center.

The patient either sat or reclined on the uranium padded bench while undergoing the "treatment" provided by the purported radioactivity of the ore. The loose pads were provided the patient for placing over affected portions of the body while he was being "treated" in the sitting room.